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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/750,921

12/31/2003

Rance A. Winkler

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1909

38732

7590

09/25/2009

CYTYC CORPORATION

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EXAMINER

LACYK, JOHN P

ART UNIT

PAPER NUMBER

3735

MAIL DATE

DELIVERY MODE

09/25/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/750,921	Applicant(s) WINKLER, RANCE A.	
	Examiner John P. Lacyk	Art Unit 3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 July 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above claim(s) 12-37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/13/09 has been entered.

Claims 12-37 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 4/29/08.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-6 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Clayton (3,872,856).

Clayton discloses a device that is used to space a radiation therapy device from the walls of tissue in the body. Clayton has an insertion member (11) having a proximal

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end and a distal end; a spacing element (13 or 14) disposed on the distal end of the insertion member, the spacing element movable between a closed position (deflated) and an open position (inflated) and when inflated would have a predeterminable height. The spacing element is used to contact an outer surface of a brachytherapy device or radioactive material (25-26) and the tissue or wall of the body within a cavity. While Clayton does not specifically teach using the device in a "surgical extraction site" or cavity this is directed to the intended use of the spacing device and the device of Clayton is clearly capable of being used in such a manner. Clayton clearly teaches all of the claimed structure of the spacing apparatus. With respect to claim 6, the spacing element (13) is considered to be a substantially disk shaped balloon.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 7-8 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Clayton in view of Flexmedics Brochure.

Clayton discloses the claimed device except for specifically using a shape memory material. The Flexmedics Brochure teaches that it is well known to use a shape memory material with many different medical devices including catheters. Therefore a modification of Clayton such that the spacing element or balloon catheter is made from a shape memory material would have been obvious to one skilled in the art in view of

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the teachings of Flexmedics which shows that such a material is well known in the art. Further one would have been motivated to modify the Clayton device since this would be the mere substitution of one known way to inflate the balloon for another and allow the balloon to inflate without the need for using a fluid to inflate.

Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Clayton in view of Williams et al (5,913,813).

Clayton, as discussed above, teaches a radiation therapy device used within the body but does not specifically teach the use of a radio-opaque material. Williams et al discloses a catheter for treatment of proliferative tissue using brachytherapy. Williams et al discloses a spacing element or apparatus (36) in the form of an expandable balloon, which is "integrally formed" with the insertion member (12) and positions the brachytherapy device at a distance apart from the surrounding tissue, equal to the height of the balloon. The spacing element is movable between a deflated closed position and an inflated open position. Williams et al further teaches that the spacing element forms a radio-opaque barrier between the brachytherapy device and the surrounding tissue when expanded (column 2, lines 49-50). Therefore a modification of Clayton to include a radio-opaque barrier would have been obvious to one skilled in the art in view of Williams et al which teaches that it is well known to use a radio-opaque barrier with radiation therapy within the body.

Claims 1-6, 9-10 are rejected under 35 U.S.C. 102(e) as being anticipated by Green et al (6,422,997).

Green et al discloses a disk shaped balloon catheter having an insertion member (32) having proximal and distal ends and a spacing element or disk shaped balloon (34) disposed on the distal end. When inflated the balloon has a “predeterminable height”. While Green et al does not specifically teach using the device to contact an outer surface of a brachytherapy device and tissue at a surgical extraction site to space the brachytherapy device a distance apart from the tissue, this is considered to be directed to the intended use of the device. Green et al discloses all of the claimed structure of the “spacing apparatus” and is clearly capable of being used with a brachytherapy device to space the brachytherapy device from tissue within a body. Green et al also teaches that the device may be radiopaque (abstract).

Claims 7-8 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Green et al in view of Flexmedics Brochure for the same reasons as discussed above.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John P. Lacyk whose telephone number is (571)272-4728. The examiner can normally be reached on 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Chuck Marmor, II can be reached on 571-272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

J.P. Lacyk

/John P Lacyk/
Primary Examiner, Art Unit 3735